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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,919	03/15/2001	Hiroshi Sano	026350-048	2905

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EXAMINER
COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
1638	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No. 09/805,919	Applicant(s) SANO ET AL.	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover she t with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1,2 and 7-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group III, claims 5-6, in Paper No. 8 is acknowledged. The traversal is on the ground(s) that Groups II and II are not distinct, as the nucleotide sequence of Group II, SEQ ID NO:2, and Group III, SEQ ID NO:3, are from the same C7 gene, SEQ ID NO:3 being the C7 cDNA sequence, and SEQ ID NO:2 being the ORF of the C7 cDNA sequence. Because the nucleotide sequences of Groups II and III are not distinct, Groups II and III are rejoined, and claims 3-6 are examined on the merits in the instant office action.

The traversal is also on the ground(s) that Group I is not distinct and independent from the invention relating to SEQ ID NO:2 and the additional search of Group I would not be seriously burdensome, Groups IV and VI are related and connected in operation and not independent from each other and the additional search of Groups IV and VI would not be seriously burdensome, and Groups V and VII not distinct and independent from the inventions of Groups I, II, III, IV and VI and the additional search of Groups V and VII would not be seriously burdensome. This is not found persuasive because an application may properly be required to be restricted to one of two or more claimed inventions if they are either independent *or* distinct (MPEP § 803). However, since the nucleotide sequences of Groups II and III are not distinct, Groups IV and VI, drawn to methods to render resistance to an environmental stress to a plant using the nucleotide sequences of Groups II and III, are rejoined. Likewise, Groups V and VII drawn to transgenic plants comprising the nucleotide sequences of Groups II and III and exhibiting resistance to an environmental stress, are rejoined. This is also not found persuasive because while the search of Groups I and IV-VII may overlap with the search of Groups II and

III, their searches are not coextensive of each other. In this particular instance, a search of Groups I and IV-VII is not coextensive with a search of Groups II and III, since Groups I and IV-VII require a searches for a polypeptide, stress resistant plants, and methods of rendering resistance to environmental stress to plants, all of which are not claimed in Groups II-III. Accordingly claims 1-2 and 7-18 are withdrawn as being drawn to nonelected inventions, and claims 3-6 are examined on the merits in the instant office action.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 15 March 2000. It is noted, however, that applicant has not filed a certified copy of the 2000-71,655 application as required by 35 U.S.C. 119(b).

Claim Objections

Claims 3 and 4 are objected to because of the following informalities: claims 3 and 4 depend from a claim to a nonelected invention. Appropriate correction is required.

Specification

The abstract of the disclosure is objected to because the form and legal phraseology used in patent claims, such as 'means' and 'said' is included. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-6, and claim 1 to the extent that its limitations are incorporated into claims 3 and 4, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation of "amino acids numbered by Nos. 1-308 shown in SEQ ID NO:1". Reference to the numbering is confusing, since SEQ ID NO:1 is exactly 308 amino acids long. It is suggested that the claim be amended to delete reference to the amino acid numbering.

Claims 1, 4 and 5 are indefinite in the recitation of "in a sequence listing thereof", because there is no antecedent basis in the claims. It is suggested that the claims be amended to delete "in a sequence listing thereof".

Claims 1 and 5 are indefinite in the recitation of two colons in the claim. The relationship between the different subparts of each claim is unclear. It is suggested that the claims be amended to replace the second colon with a comma.

Claims 3-6 are indefinite in the recitation of "gene". The word gene implies DNA existing in nature that includes coding regions and noncoding regions, such as enhancers,

promoters, and introns. It is suggested that the claim be amended to recite "isolated polynucleotide" or "isolated nucleic acid".

Claim 4 is indefinite in the recitation of "bases numbered by Nos. 1-927 shown in SEQ ID NO:2". Reference to the numbering is confusing, since SEQ ID NO:2 is exactly 927 bases long. It is suggested that the claim be amended to delete reference to the base numbering.

Claim 5 is indefinite in the recitation of "bases numbered by Nos. 1-1210 shown in SEQ ID NO:3". Reference to the numbering is confusing, since SEQ ID NO:3 is exactly 1210 bases long. It is suggested that the claim be amended to delete reference to the base numbering.

Claim 5 is indefinite in the recitation of (c) and (d), because claim 5 recites no subparts (a) and (b). It is suggested that the claim be amended to recite (a) and (b) in place of (c) and (d).

Claim 5 is indefinite in the recitation of "hybridizes with said base sequence (c) under stringent condition". It is unclear what conditions would yield the claimed base sequence. It is suggested that the claims be amended to recite specific hybridization conditions.

Claim 5 is indefinite in the recitation of "the base sequence (d) being induced by an environmental stress". It is unclear what type of induction is being referred to.

Claims 1, 4 and 5 are also generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. Specific examples of such errors include "an amino acid sequence consists of amino acids", "a base sequence consists of bases", "of following (c) or (d)", and "under stringent condition". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 3-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to a gene, and are thus drawn to a product of nature. It is suggested that the claims be amended to recite "isolated polynucleotide" or "isolated nucleic acid" rather than "gene" in order to overcome the rejection.

Claims 3-6 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The claims are drawn to a gene encoding a polypeptide of SEQ ID NO:1 and a gene encoding a polypeptide induced by an environmental stress said polypeptide having an amino acid sequence of SEQ ID NO:1 in which amino acid deletions, additions or substitutions have been made. The claims are also drawn to a gene consisting of SEQ ID NO:2, SEQ ID NO:3, or a base sequence induced by an environmental stress that hybridizes under stringent conditions to SEQ ID NO:3.

First, the claims do not recite a specific function for SEQ ID NO:1, or for polypeptides having an amino acid sequence of SEQ ID NO:1 in which amino acid deletions, additions or substitutions have been made. The claims also do not recite a specific function for the polypeptide encoded by a base sequence that hybridizes under stringent conditions to SEQ ID NO:3. The recitation that a polypeptide or base sequence is induced by an environmental stress is not a specific function, as many structurally and functionally distinct polypeptides and base sequences are induced by environmental stress. In the absence of a specific functional limitation,

one could not identify useful polypeptides having an amino acid sequence of SEQ ID NO:1 in which amino·acid deletions, additions or substitutions have been made, since some of these changes would inactivate the function of the polypeptide. Likewise, in the absence of a specific functional limitation, one could not identify useful polypeptides encoded by a base sequence that hybridizes under stringent conditions to SEQ ID NO:3, since some of the hybridizing sequences would encode a nonfunctional polypeptide. Because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be assessed.

Second, the claimed invention lacks utility because no function has been demonstrated for SEQ ID NO:1. Although the specification suggests that expression of SEQ ID NO:1 in a transgenic plant would increase the plant's stress resistance (page 2), and that SEQ ID NO:1 has homology to receptor-like kinases (page 16), no empirical data is provided to support a stress resistance function or a receptor-like kinase function for SEQ ID NO:1. While empirical data is not required for patentability, the state of the art recognizes that a functional assignment based on amino acid homology may be useful to categorize a sequence as potentially encoding a particular protein or provide a starting point for verifying the function of the protein it encodes, it does not replace empirical data for confirming its function.

Third, Applicant's claimed nucleic acid sequence lacks substantial utility under current utility guidelines. Although the specification suggests that expression of SEQ ID NO:1 in a transgenic plant would increase the plant's stress resistance (page 2), and that SEQ ID NO:1 has homology to receptor-like kinases (page 16), the specification does not disclose any effect of expressing SEQ ID NO:1 in a transgenic plant, or whether SEQ ID NO:1 has a receptor-like kinase activity. Applicant does not teach how the claimed nucleic acid sequence would be substantially beneficial to the public. Environmental; stress encompasses a wide range of

conditions and is not specific and thus cannot be tested. Further, the state of the art recognizes multiple proteins which are involved in specific stress tolerance conditions such as high salinity, drought, etc. No one protein is known to confer tolerance to all environmental stresses or diverse stress conditions. Applicant has not shown that SEQ ID NOS: 2 or 3 or their expression would enhance environmental stress tolerance. It is apparent that further research, not considered to be routine experimentation, would be required before one of skill in the art would know how to use the claimed invention. It has been established by the courts that a utility which requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use is not a substantial utility.

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." (*Brenner v. Manson*, 383 U.S. 519 (1966)).

Thus, while a nucleic acid sequence that confers stress tolerance when expressed in a transgenic plant has substantial benefit to the public, Applicant does not disclose such a nucleic acid, and one skilled in the art cannot conclude that SEQ ID NOS:2 and 3 would confer stress tolerance when expressed in a transgenic plant based upon Applicant's disclosure. Applicant's invention is not refined to the point where specific benefit exists in currently available form. As set forth above, one skilled in the art cannot readily take Applicant's claimed invention and derive immediate benefits from it based upon Applicant's disclosure. Accordingly, the claimed invention lacks a real world use. (see Utility Examination Guidelines published in the Federal Register, Vol. 66, No. 4, Friday, January 5, 2001, Notices, pages 1092-1099).

Claims 3-6 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Remarks

The claims are deemed free of the prior art of record, since the prior art fails to teach or suggest an isolated nucleic acid of SEQ ID NOS:2 or 3, or an isolated nucleic acid encoding a polypeptide of SEQ ID NO:1.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
June 28, 2002

Phuong Bui 7/1/02
PHUONG T. BUI
PRIMARY EXAMINER